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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,995	07/11/2003	Ilan Calderon	1311OBT-US	2778

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EXAMINER

NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/616,995	Applicant(s) CALDERON ET AL.	
	Examiner Helen Nguyen	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the RCE filed 10/05/2006. In view of the amendment to independent Claim 1, the previous §112 first and second rejections based upon the claim language “a function” is considered moot. The indicated allowability of **Claims 1-7** is withdrawn in view of the rejection based upon the amended claim language, shown below. Amendments to Figure 2 of the drawings and the specification filed 8/14/2006 are accepted. However, the drawing rejection still remains, as described below.

Drawings

2. The drawings of **Figure 2** are objected to under 37 CFR 1.83(a) because they appear to fail to clearly show the three-dimensional image of muscle contraction as sensed by the claimed position sensing system, as described on p.5 of the specification. The inclusion of element numbers has enhanced the objected drawing, however it is still not understood how “44” shows a three-dimensional image of muscle contraction. Applicant is reminded that no new matter may be added while overcoming this drawing objection.

3. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from

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the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **Claim 6** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

6. The disclosure fails to describe or teach one of ordinary skill in the art how the claimed processor operative to process data of the claimed EMG system, said CTG monitor, and the claimed three-dimensional position information from the at least one position sensor would provide an output that comprises electromyographic activity data and CTG data as a function of the three-dimensional position of said at least one position sensor. The disclosure fails to

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describe or teach one of ordinary skill in the art exactly what is meant by electromyographic activity data and CTG data as “a function of” three-dimensional position of the at least one position sensor.

7. Examiner notes that said subject matter is only mentioned on p.2 and p.4 (last paragraph) of the specification, using the same language as that recited in the claims. This rejection is analogous to the previous §112 rejection of Claim 1.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. **Claim 6** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, also evidenced by the enablement problem associated with the disclosure.

10. Specifically, one of ordinary skill in the art is not able to clearly point out and distinctly identify how the claimed processor operative to process data of the claimed EMG system, said CTG monitor, and the claimed three-dimensional position information from the at least one position sensor would provide an output that comprises electromyographic activity data and CTG data as a function of the three-dimensional position of said at least one position sensor. Thus, the claim is indefinite because it fails to distinctly point out to one of ordinary skill in the art exactly what is meant by electromyographic activity data and CTG data as “a function” of three-dimensional position of the at least one position sensor. This rejection is also analogous to the previous §112 rejection of Claim 1.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. **Claims 1-3 and 5-7** are rejected under 35 U.S.C. 103(a) as being unpatentable by Garfield et al (US Pat No. 6816744) in view of Krausman et al (US Pat No. 6095991).

13. In regards to **Claim 1**, Garfield et al disclose an electromyogram (EMG) system operative to sense electromyographic activity generated in muscle (Figure 8). However, Garfield et al do not disclose a position sensor. Krausman et al disclose at least one position sensor used to detect three-dimensional position information (Figure 3A and 3B), one application of which is to integrate the sensor with other medical monitoring instruments, to gain a better understanding of the physiological function being measured (Col8, line 22-27). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to use a position sensor as disclosed by Krausman et al in conjunction with another medical monitoring instrument such as the EMG system of Garfield et al to allow better monitoring of electromyographic activity.

14. Garfield et al also disclose determining the position of electrical muscular activity signals (Col.29, line 50-61). Therefore, Garfield et al as modified by Krausman et al make obvious to one of ordinary skill in the art at the time the invention was made, in combination, the determination of the three-dimensional position of said electrical muscular activity signals, as modified as such for the reasons stated above.

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15. Garfield et al also disclose a processor (22), referred to as "computer," in communication with said EMG system, operative to process electrical muscular activity signals of said EMG system and as well as other types of data, i.e. cardiac and brain activity (Col.8, line 20-30).

Therefore, Garfield et al as modified with Krausman et al make obvious to one of ordinary skill in the art at the time the invention was made, in combination, said processor operative to process electrical muscular activity signals of said EMG system and another type of data such as the three-dimensional positions of said electrical muscular activity signals (as explained above), the modification of which as motivated by the reasons cited above.

16. Furthermore, Garfield et al disclose the analysis and subsequent display of more than one of type of data at the same time, as exemplified in Figure 3 (Col.14, line 62-67). Therefore, Garfield et al as modified with Krausman et al make obvious to one of ordinary skill in the art at the time the invention was made, in combination, the output and display of said electrical muscular activity signals and their three-dimensional positions at the same time, the modification of which as motivated by the reasons given above.

17. Thus, it is shown that Garfield et al as modified by Krausman et al disclose in combination an EMG system, at least one position sensor, and a processor in communication with said EMG system and said at least one position sensor, said processor operative to process electrical muscular activity signals of said EMG system and three-dimensional positions of said electrical muscular activity signals from said at least one position sensor to provide an output and display of said electrical muscular activity signals and their three-dimensional positions at the same time.

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18. In regards to **Claim 2**, Garfield et al disclose an EMG system comprising of at least one EMG sensor (201-204) and at least one reference EMG sensor (205) adapted to sense electromyographic activity generated in a muscle of interest and in a reference muscle, respectively (Col.23, line 20-22).

19. In regards to **Claim 3**, Garfield et al disclose a monitor (23) coupled to the processor to display the processed information from the processor.

20. In regards to **Claim 5**, Garfield et al disclose a fetal cardiac unit (403) and tocodynamometer (401) as standard clinical devices useable in conjunction with the invention (Figure 7). Such standard devices inherently comprise of sensors used to obtain the necessary data. Thus, the fetal heart rate (FHR) sensor and TOCO sensor disclosed by Garfield et al may be referred to collectively as a CTG monitor. These sensors are connected to the EMG system, which in turn, are connected to the previously mentioned processor.

21. In regards to **Claim 6**, the collective CTG system comprising of fetal heart rate and TOCO sensors are connected to said processor. Garfield et al disclose sensors (17), such as those for fetal heart rate and TOCO of the collective CTG monitor, connected to the processor or “computer” (22) in Figure 1. Krausman et al also disclose a “microprocessor” (Figure 2 or Col.4, line 24-29) to output analyzed positional data. Thus, when used in conjunction with one another, the processor of Garfield et al is operative to process data from the collective CTG monitor along with data from said EMG system and at least one position sensor, as disclosed by Krausman et al, to provide electromyographic activity and CTG data **as a function of** the three-dimensional position.

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22. In regards to **Claim 7**, Garfield et al disclose a warning mechanism in communication with the processor, operative to issue a warning if the processed data processed by said processor is above a predefined limit, or other abnormalities, are found (Col.16, line 26-28).

23. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al in view of Krausman et al, further in view of Triano (US Pat No. 5991701).

24. Krausman et al disclose a position sensing system but do not disclose measuring the three-dimensional position and orientation of said position sensor with respect to a reference position. Triano discloses an invention comprising of positional sensors (S1 and S2) to determine the corresponding three-dimensional positions (Col.3, line 19-20) as the sensors move, one in reference to the other (Col.3, line 2-3, 14-17). To measure three-dimensional position, namely in accordance with a coordinate system, a reference position must be present to accurately capture such data. This is disclosed in reference by Triano to US Pat. No 3868565 (Col.1, line 46-48). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to place position sensors in Garfield et al, as modified by Krausman et al, relative to each other, as taught by Triano, to accurately display position information as it is well known in the art that any sort of measurement of distance requires a reference point upon which measurements must be based, particularly for three-dimensional coordinate data.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Koeneman et al (US Pub No. 20040267331) disclose an EMG system in combination

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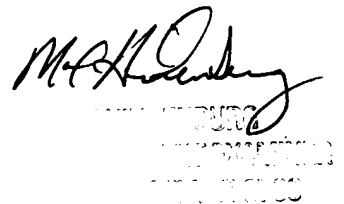
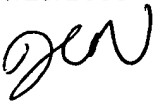
with a position sensing system. Finneran et al (US Pat No. 6745062) disclose an EMG electrode apparatus and positioning system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HQN
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OCT 25 2006